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CANADIAN PATENT

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**DEVICE FOR PROTECTION OF PATIENTS AGAINST EXCESSIVE
ELECTRICAL CURRENTS**

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No. OF CLAIMS 11

Abstract of the Disclosure

A device for protecting patients against excessive currents which might flow through the patients from medical electrical equipment. A full-wave diode bridge rectifier circuit is connected between the patient and ground and provides a low-impedance path between the patient and ground. A constant current source is connected to the bridge circuit to forward-bias the diodes. The current allowed to flow between the patient and ground is limited to the current supplied by the current source.

This invention relates to medical instrumentation equipment; more particularly, this invention relates to devices for protecting patients from receiving electrical shocks from medical instrumentation equipment.

5 The problem of preventing patients from receiving shocks from electrical medical instrumentation is both serious and difficult to solve. The problem is serious because a substantial number of injuries and deaths occur due to patient electrocution in hospitals every year. The problem is
10 difficult to solve because the constantly increasing proliferation of medical electronics equipment currently in use greatly increases the potential sources of shocks to the patient. Furthermore, with equipment utilizing probes inserted into the flesh or blood vessels of the patient, much less
15 current flow through the patient is required to cause permanent damage or death to the patient than if external probes were used. Thus, currents through the patients must be limited to very low values at all times for maximum safety. However, much medical electronic equipment requires the provision of a
20 low-impedance path between the patient and ground. This requirement makes it difficult to limit the current to very low values.

In accordance with the foregoing, it is a major object of the present invention to provide medical instrumentation
25 apparatus which limits the flow of electric current through a patient's body to a very low level, and yet provides satisfactory ground connections for the electrical equipment. It is another object of the present invention to provide such equipment which is relatively simple in construction, reliable in operation,
30 and inexpensive to build and maintain.



In accordance with the present invention, the foregoing objects are met by the provision of a patient protection device in which unidirectional conduction means are connected between the patient and ground in a medical instrumentation system. A constant current source supplies forward bias current to the unidirectional conduction means, and the current flow between the patient and ground is limited to the amount of the forward bias current.

The foregoing and other objects and advantages of the inventions will be set forth in or apparent from the following description and drawings:

In the drawings:

Figure 1 is a schematic circuit diagram of a medical instrumentation system constructed in accordance with the present invention; and

Figure 2 is a schematic circuit diagram of another embodiment of the present invention.

Figure 1 shows a medical instrumentation system 10 including a ground current protection device constructed in accordance with the present invention. The ground circuit protection device comprises a current-limiting circuit including a constant current source 12 and a full-wave diode bridge rectifier circuit 14. A medical instrument 28 has measurement leads 30 connected to a patient 32. It also has an instrument ground connection 24; and a power source ground connection 26. The body of the patient 32 is connected to instrument ground 24 through the rectifier bridge 14.

The bridge circuit 14 consists of 4 silicon diodes 16, 18, 20 and 22 connected in a bridge arrangement. The positive output terminal of the current source 12 is connected to the corner of the bridge which is connected to

the anodes of the diodes 16 and 18. The negative terminal of the source 12 is connected to the cathodes of the diodes 20 and 22. Thus, the current source 12 supplies forward bias current for all of the diodes in the rectifier bridge circuit 14. The junction between the cathode of diode 16 and the anode of diode 22 is connected to the instrument ground lead 24, and the opposite corner of the bridge is connected to the patient through a lead 34.

A low-impedance path from the patient to ground often is required by modern medical electronic equipment. Such equipment includes electrocardiograph recorders, electroencephalograph recorders, etc. The reference numeral 28 can be considered to be any one of such instruments. When the bridge is balanced, as it is when there are no currents flowing from the patient to ground, the impedance through the bridge between the patient and ground is equal to the forward impedances of diodes 16 and 18 in parallel with the forward impedances of diodes 20 and 22. This impedance is low, and the bridge thus provides, effectively, the low-impedance path needed by the electronic equipment 28. For example, typically the forward impedance of each diode at 5 microamperes bias current is 20,000 ohms. Thus, the total impedance in each branch of the path through the bridge is 40,000 ohms, and the total bridge impedance is 20,000 ohms. This impedance is relatively low, so that the path through the bridge is the low impedance path needed by the equipment 28. When a diode is back-biased, its impedance and the bridge impedance both increase to a very large value, e.g. 100 megohms or more.

If current starts flowing from the patient 32 to ground 24, the current flow in diodes 18 and 22 decreases while the current in diodes 16 and 20 increases until finally diodes 18 and 22 become back-biased and present a very high impedance

to the flow of additional current. The current at which this occurs is equal to the bias current supplied by the current source 12. Similarly, if current flows from ground 24 to the patient 32, the diodes 16 and 20 become back-biased when the
5 current reaches the level of current supplied by the source 12, and the current does not increase significantly after that. Thus, the flow of current between the patient and ground is limited to the bias current supplied by the current source 12.

It has been determined that in order to protect
10 patients against electrical shock, the current through their bodies from electronic instrumentation should be limited to as low as 10 micro-amperes (10 millionths of an ampere). Since the circuit 10 limits the flow of current through the patient's body to the output current of the current source 12, the output
15 current of source 12 preferably is maintained at or below 10 micro-amperes.

Figure 1 shows, in dashed outline, a fault voltage source 36 which is connected to power supply ground over a lead 37. Such a fault source might be, for example, a faulty power
20 supply of another instrument connected to the patient. In such an instance, rather than being electrocuted, the patient will suffer no ill effects because the current-limiting device limits the current through the patient's body to 10 micro-amperes.

The power ground connection is provided, for example,
25 by the usual 60-cycle wall outlet found in hospitals and homes, or other known means.

The constant-current source 12 can be any of a number of well-known high-impedance devices, such as the well-known constant-current sources using field effect transistors or
30 bi-polar transistors.

The rectifier bridge circuit 14 can be composed of discrete components, or it can be one of a number of full-wave rectifier devices which are sold as a complete unit. One such unit which has been found to be satisfactory is sold by the
5 Varo Corporation under the identification number "VE 48".
The breakdown voltage of the bridge should be at least equal to the maximum signal voltages to be encountered in the system. A breakdown voltage of at least 400 volts has proved to be satisfactory.

10 The patient protection circuit described above performs the dual function of providing a low-impedance ground connection to the patient which is required by many types of modern medical or electronical equipment, and yet limits the
15 flow of current through the patient's body, in case of faults or other potential sources of electrical shocks, to currents which are well below maximum safe levels. The patient protection device is simple, relatively inexpensive and reliable.

Figure 2 shows an alternative embodiment of the present invention which is the same as that shown in Figure 1, with
20 certain exceptions. The same reference numerals are used to identify the same components in both figures of the drawings.

One way in which the system shown in Figure 2 differs from that shown in Figure 1 is that a constant current supply is formed by two separate constant current sources 12 connected
25 in series, with the common point between the two current sources connected to ground 24 through a lead 38. Each of the sources 12 produces a constant current of 10 micro-amperes, and the bridge circuit 14 operates as described above. The use of two sources 12 instead of one can reduce the cost of the system in
30 that it allows the use of commonly-available, relatively

inexpensive power supplies which produce positive and negative voltages with respect to ground rather than the sometimes more expensive floating supply which is needed for the system shown in Figure 1.

5 Figure 2 also shows, in addition to the patient 32, a second patient 42, and shows a second medical electrical instrument 28 connected to the patient 42, as well as third medical instrument 40 also connected to the patient 42 through a pair of signal leads 44. The instrument 40 is connected to its
10 instrument ground through a lead 48.

The power ground connection for the unit 40 is shown as if it were broken at 50. Under such circumstances, currents might be induced from instrument 40 through patient 42 to power ground 26. However, the current-limiting circuit of the
15 present invention prevents this from occurring and thus prevents injury to the patient 42.

The present invention can be used in several different ways to protect significant numbers of patients in hospitals or similar places. One such way is to protect each patient
20 with his own individual limiting circuit, as is shown in Figure 1. Another way is to provide only one ground connection and only one limiter in the ground connection, as is shown in Figure 2. In either arrangement, the invention provides maximum safety for the patients.

25 The above description of the invention is intended to be illustrative and not limiting. Various changes or modifications in the embodiments described may occur to those skilled in the art and these can be made without departing from the spirit or scope of the invention as set forth in
30 the claims.

1. A patient protection device for use in medical electrical instrumentation, said device comprising unidirectional conduction means, a constant current supply connected to supply forward bias current to said unidirectional conduction means, and means for connecting said unidirectional conduction means between a patient and ground to limit the amount of current which can flow between the patient and ground.

2. A device as in Claim 1 including at least one physiological electrical instrument with a ground terminal connected to said ground and at least one signal terminal connected to said patient.

3. A patient protection device for use in medical electrical instrumentation, said device comprising a full-wave diode bridge rectifier circuit, a constant current supply connected to two opposite corners of said bridge circuit so as to provide forward bias current to each of the diodes in said bridge circuit, and means for connecting one of the other corners of said bridge circuit to ground and the remaining corner to a patient.

4. A device as in Claim 3 in which said current supply includes two separate current sources, one connected to one of said opposite corners, and the other connected to the other of said opposite corners, said sources being connected together in series, and the common connection between them being connected to ground.

5. A device as in Claim 3 in which the positive terminal of said constant current supply is connected to the anodes of two of said diodes, and the negative terminal of said constant current supply is connected to the cathodes of the other two diodes.

6. A device as in Claim 3 including at least one physiological electrical instrument with a ground terminal connected to said ground and at least one signal terminal connected to said patient.

7. A medical instrumentation system, said system comprising a plurality of electrical physiological devices, each of said devices having an instrument ground lead, means for connecting each of said ground leads together to form a common instrument ground point, unidirectional conduction means, a constant current supply connected to supply forward bias current to said unidirectional conduction means, and means for connecting said unidirectional conduction means between said common instrument ground point and at least one patient to limit the amount of current which can flow between the patient and said ground point.

8. A system as in Claim 7 in which said unidirectional conduction means comprises a full-wave diode bridge rectifier circuit, and a constant current supply connected to two opposite corners of said bridge circuit so as to provide forward bias current to each of the diodes in said bridge circuit, and said connecting means includes means for connecting one of the other corners of said bridge circuit to ground and the remaining corner to a patient.

9. A system as in Claim 7 in which said connecting means includes means for connecting said unidirectional conduction means between said common ground point and a plurality of patients.

10. A system as in Claim 8 in which said current supply includes two separate current sources, one connected to one of said opposite corners, and the other connected to the other of said opposite corners, said sources being connected together in series, and the common connection between them being connected to ground.

11. A patient ground circuit protection device for use in medical instrumentation, said device comprising variable impedance means for presenting a relatively low impedance between two terminals to currents below a pre-determined maximum level, and for changing said impedance to a relatively very high value to currents above said level, and means for connecting said terminals of said variable impedance means between a patient and ground.



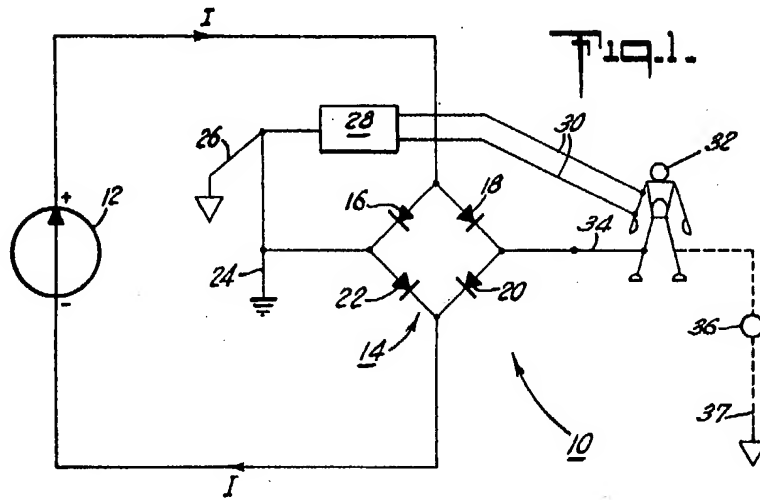
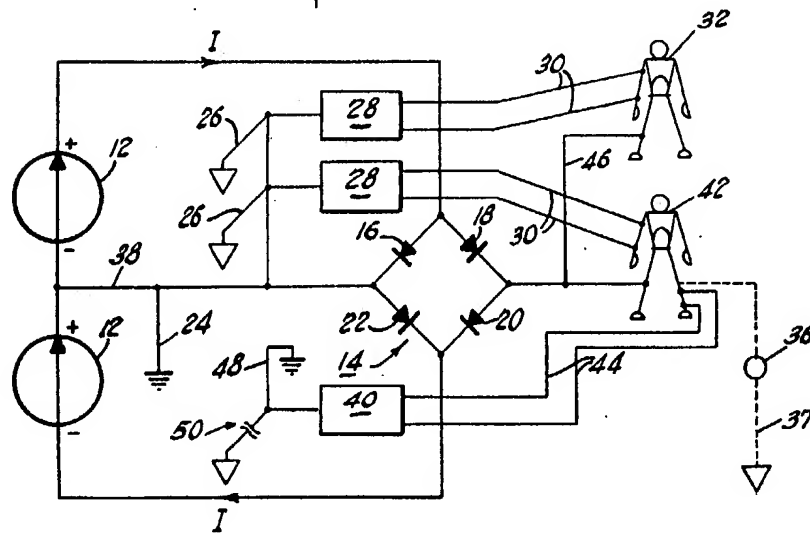


Fig. 2.



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